

695 South Colorado Boulevard  
Suite 320  
Denver, Colorado 80246  
www.corneas.org  
(303) 778-0282  
FAX (303) 778-0428

Toll Free (800) 444-7479



Richard Damiano, M.D.  
Medical Director

S. Lance Forstot, M.D.  
Medical Director

Edmund P. Jacobs  
CEO

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ACCREDITED MEMBER  
EYE BANK ASSOCIATION of AMERICA



December 23, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5360 Fishers Lane, rm. 1061  
Rockville, MD 20852

Re.: 21 CFR Parts 210, 211, 820, 1271 [Docket no. 97N-484S]

The staff of the Rocky Mountain lions Eye Bank have reviewed the above referenced regulation and offer comments on the proposed rule.

**Summary:**

*We are supportive of:*

1. Screening of eye donors to rule-out prion disease via an interview with knowledgeable next-of-kin. § 1271.3 (o)
2. Blood testing for syphilis. § 1271.85 (a) (b) (c)

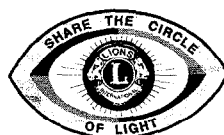
*We are not supportive of:*

3. Artificially imposed time limits for serum storage prior to testing. § 1271.80 (b)
4. Brain biopsies to rule-out prion disease. *Specific Req. § 1271.85 4. Corneal Tissue*

**Comments:**

1. Creutzfeldt-Jakob Disease (CJD) is a fatal disease demonstrated to be spread via corneal transplantation. The Rocky Mountain Lions Eye Bank has conducted medical/social history screening to rule-out donors who may exhibit signs and symptoms of prion disease. Our questions posed to next-of-kin are:

- "Did the deceased suffer from any type of neurologic brain disorder such as Alzheimer's, seizures, periods of confusion or recent memory loss, history of brain tumor?"
- "Was the deceased ever diagnosed with Creutzfeldt-Jakob Disease?"



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- “Is there a family (blood relative) history of CJD or has the family been told they are at risk for CJD?”
- “Did the deceased receive a dura mater transplant?”

The Rocky Mountain Lions Eye Bank has discarded tissue in recent months due to concerns discovered in the medical/social history screening and believe such screening is our most relevant screening method to protect the public from transmitting prion disease via cornea transplantation. The Rocky Mountain Lions Eye Bank is willing to adopt or add appropriate questions deemed relevant by agencies such as the Eye Bank Association of America, CDC or FDA.

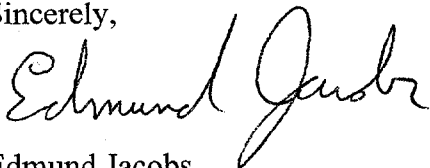
2. The Rocky Mountain Lions Eye Bank currently conducts syphilis testing for our eye donors on a voluntary basis. From time to time we receive reactive results from our testing laboratory and discard the tissue. We believe syphilis testing is a reasonable step to protect the public and support the application of the test for all transplantable eye donors.

3. The Rocky Mountain Lions Eye Bank recommends that the time constraints for storage of blood/serum prior to testing be consistent with the instructions given with the serology test kit used. Artificial time constraints referred to in the Rule may not be consistent with testing instructions published by the various manufacturers or test kits. We suggest the science applied to testing kit instructions be respected without additional guidelines being imposed.

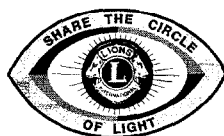
4. The Rocky Mountain Lions Eye Bank does not see relevant benefit in performing brain biopsies for all eye donors to rule-out prion disease. Corneal tissues have a short shelf life and will not survive the lengthy time needed to receive biopsy findings from pathology laboratories. We believe an in-depth medical/social history screening conducted with knowledgeable next-of-kin is the most appropriate method to rule-out prion disease in eye donors and should be the only screening standard used at this time.

I hope you find our comments and observations useful and give them appropriate consideration.

Sincerely,



Edmund Jacobs  
Chief Executive Officer





**ROCKY MOUNTAIN  
LIONS EYE BANK**

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